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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/779,638 | 02/18/2004 | Renwen Zhang | 08702.0068-01000 | 9082 |
| 22852 | 7590 | 06/14/2006 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | ROBINSON, HOPE A | |
| | | ART UNIT | PAPER NUMBER | |
| | | | 1656 | |

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------|--------------|
| Office Action Summary | Applicant No. | Applicant(s) |
| | 10/779,638 | ZHANG ET AL. |
| | Examiner | Art Unit |
| | Hope A. Robinson | 1656 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- . 4) Claim(s) 15-37 is/are pending in the application.
- 4a) Of the above claim(s) 15-19 is/are withdrawn from consideration.
- 5) Claim(s) 23,24, 26-33 and 35 is/are allowed.
- 6) Claim(s) 20 and 21 is/are rejected.
- 7) Claim(s) 22,25,34,36 and 37 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed November 18, 2005 on March 23, 2006 is acknowledged. The Terminal Disclaimer filed February 21, 2006 has been received and entered.

Claim Disposition

2. Claims 1-14 have been canceled. Claims 15-37 are pending. Claims 20-37 are under examination.

Withdrawn- Abstract Objection

3. Previous objection to the abstract is withdrawn by virtue of submission of an amendment.

New-Claim Objection

4. Claims 22, 25, 34, 36 and 37 are objected to because of the following informalities:
Claim 22 is objected to because the claim depends from a rejected based claim.
For clarity and precision of claim language it is suggested that claim 34 is amended to read, "wherein the area [of the knee] in need of regeneration of articular cartilage is the trochlear groove". See also claims 36 and 37.

Claim 25 is objected to for the recitation of "wherein said the".

Withdrawn-Claim Rejections - 35 USC § 112

5. Previous rejections to claims under 35 U.S.C. 112, second paragraph are withdrawn by virtue of submission of an amendment.

New-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 20 is directed to a method for regeneration of articular cartilage comprising administering to an area in need of regeneration of said articular cartilage an osteochondral graft having applied thereto a composition consisting essentially of an amount of a heterodimer effective for the regeneration of articular cartilage, wherein the heterodimer comprises one purified bone morphogenetic protein and one protein which induces the formation of tendon or ligament tissue. The claim does not set forth what protein is intended to "induce the formation of tendon or ligament tissue. It is noted that claim 22 provides the missing information, however, claim 20 has to stand-alone. The claimed invention is directed to a genus of protein that may exhibit the desired function, however, that are not adequately described in the instant specification. Therefore, the specification lacks adequate written description.

The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere

statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993).

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

7. Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the BMP proteins, does not reasonably provide enablement for any protein which induces the formation of tendon or ligament tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

The claims broadly recited "one protein which induces the formation of tendon or ligament" and the claims and specification are directed to "BMP-12, BMP-13 MP52 and

members of the BMP-12 subfamily". However, the claims read on any protein with the desired activity which is not supported by the instant specification. The claims encompass a genus of proteins and the specification does not provide sufficient guidance/direction pertaining to other members of the genus. Thus, undue experimentation would be required to practice the claimed invention commensurate in scope with the claims. In addition, it is highly unpredictable to test all known proteins for the desired activity.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed genus. The nature and properties of this claim is difficult to ascertain from the examples provided as one of skill in the art would have to engage in undue experimentation to practice the full scope of the claims. The specification does not provide support for the broad scope of the claims. The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

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Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Withdrawn- Basis For NonStatutory Double Patenting

8. Previous rejections to claims under 35 U.S.C. 103, obvious-type double patenting is withdrawn by virtue of submission of a Terminal Disclaimer.

Conclusion

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS (e) 9/06
Patent Examiner

HOPE ROBINSON
PATENT EXAMINER